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August 29, 2005
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Our Case No.: 1391/1532

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Sonya S. Johnson et al.

Serial No.: 10/024,631

Filing Date: December 17, 2001

For: COATED CHEWING GUM PRODUCT AND METHOD OF MAKING (as amended)

Examiner: A. Corbin

Group Art Unit No.: 1761

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Appellants herby reply to the Examiner's Answer dated June 29, 2005, which maintains all rejections previously appealed.

A. U. S. Patent No. 5,380,530 (Hill) is not an anticipating reference.

1. Claims 1-22, 25-27, 30-34 and 37

The Examiner's Answer argues that the case of *In re Arkley, Eardley, and Long*, 172 USPQ 524 (CCPA 1972) is inapposite to the rejections in the Final Rejection. The Answer argues that in Arkley there was no specific suggestion to apply the chemical reaction to the precursor of the claimed compound, which is different than the facts in the present case. Of course that is true. However, the reasoning of Arkley is applicable, and the decision of the Court of Customs and Patent Appeals is controlling. The issue is whether a rejection made under 35 U.S.C. § 102(b) is appropriate, or whether the rejection was only appropriate, if at all, under 35 U.S.C. § 103(a).

The Arkley court pointed out that the language of Section 103 states that "where the subject matter claimed 'is not *identically* disclosed or described' in 'the prior art'", then Section 103 is the proper statutory section for analysis of patentability. Id. at 526 (emphasis in original). The court went on to state, "for the instant rejection under 35 U.S.C. 102(e) to have been proper, the Flynn reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, ... but it has no place in the making of a 102, anticipation rejection." Id. (emphasis in original).

Thus the test is whether the rejection can be made simply by following the teachings of the Hill references without any picking or choosing various parts of the disclosure. The Examiner's Answer recognizes that picking and choosing is going on in making the present rejection, but then argues that the amount of picking and choosing "is not nearly as extensive as appellant suggests." Answer, page 3. However, it was the Arkley court that dictated the language, "without *any* need for picking, choosing, and combining various disclosures." 172 USPQ at 526 (emphasis in original).

The Answer repeats the arguments in the Final Rejection, that the picking and choosing in this case is different than in Arkley because the picking and choosing is only from a limited number of "other substances" and a limited number of sweetening

agents." Answer, page 5. However, the Answer fails to even address the point made in Appellants brief, that these are each optional materials, and the decision to include a therapeutic material in the Hill emulsion coating is also optional. There is nothing in the Answer or in the Final Rejection that explains why one following the teachings of Hill would first choose to include something from all three groups of optional ingredients (therapeutic materials, "other substances" and sweetening agents), let alone selecting the right one out of the various optional ingredients listed to come up with the claimed invention.

Claim 1 requires a coated chewing gum product with absorption acceleration of a medicament, the chewing gum coating including a polyol selected from the group of sorbitol and xylitol, the coating also containing the at least one medicament, and a bicarbonate salt incorporated into the chewing gum center, coating or both. Hill discloses oral hygiene preparations, including coated chewing gum that use a special coating made from an emulsion containing an ingestible surfactant and a polydimethyl siloxane. The material is designed to disrupt dental plaque. These are the only required elements of the product in Hill. All the rest, which the Examiner picks and chooses to come up with the claimed invention, are optional. The "other substances" are not a necessary part of the Hill invention. Likewise, the sweetening agents listed in column 17, lines 33-38, are optional. This is on top of the fact that, if one were to decide to include one of each of these three different materials, there would still likely be millions, if not billions, of different combinations of ingredients suggested for use in the emulsion coating. Yet only a handful of these combinations would have all three of a medicament, sodium bicarbonate and xylitol and/or sorbitol as required by claim 1. Just as in *Arkley*, one has to pick and choose specific ingredients from unrelated parts of the disclosure, in this case lists of numerous optional ingredients, to come up with all of the items required by claim 1. And, just as in *Arkley*, there are examples in Hill, but none of the examples teach the claimed combination. Nor is there anything in Hill that would make the claimed combination more likely to be used than any other possible combination of optional ingredients. Thus there is no "identical" disclosure of the invention of claim 1 in Hill as required for a rejection under 35 U.S.C. § 102(b). Hence,

just as in *Arkley*, the rejection based on Section 102 is not appropriate and must be overturned, because Hill does not identically disclose the invention of claim 1.

2. Claims 2, 4, 18 and 31

Claims 2, 18 and 31 require the bicarbonate salt to comprise from about 0.1% to about 1% by weight of the chewing gum product. Claim 4 requires sodium bicarbonate to comprise from about 0.2% to about 0.7% by weight of the chewing gum product. While there is no suggestion in Hill of using sodium bicarbonate at this level, the Answer points to Table II of Hill, which gives an example that uses 10 to 30% silica as an abrasive in the emulsion coating, and then argues that since silica and sodium bicarbonate are both listed as "other substances", they would have been used at the same levels. In fact, in column 16, lines 6-13, where they are listed, there is not even a discussion of what function these "other substances" play in the Hill product. Some of the substances are completely different in nature. For example, lecithin and lanolin are in the same list of "other substances" as the silica. There is no reason to think they would be used at the same level as silica. It is uncertain why sodium bicarbonate is in the list. It may be because it is sometimes used as a tooth whitener. The statement in the Answer that "it follows that the same amount of one of the 'other substances' would also be used at the same level" has no basis in fact. The amount of sodium bicarbonate that would be used if one happened to choose this specific "other substance" is thus not suggested in Hill, and these claims are further patentable.

3. Claim 37

Claim 37 is a method claim that requires the medicament to be delivered at a rate greater than 30% more than the rate that the medicament would have been delivered if the bicarbonate salt were not present. There is no suggestion in Hill of generating greater absorption of the medicament by the inclusion of the bicarbonate salt. The Answer takes the position that this delivery rate is an inherent result of including sodium bicarbonate in the chewing gum, and then Hill would have the same result. In this case, inherency cannot be relied upon. A reference inherently discloses something only if it is a necessary consequence that always follows from following the explicit teachings of the reference. First, it should be noted that the Hill reference teaches an oral hygiene preparation. The therapeutic materials, if they are included at

all, are designed to affect the oral hygiene of the user, and are selected for their effect in the mouth. There is no suggestion that any of the therapeutic substances used in Hill are absorbed through the oral mucosa, or that anyone would want them to be. They are chosen for the effect they have on the surfaces in the mouth, and to kill germs in the mouth. On the other hand, the present invention has to do with increasing the rate of absorption of medicaments that are absorbed through the oral mucosa, and have a systemic effect on the body. For example, caffeine is only effective as a stimulant once it is absorbed into the blood stream. This is quite different than the therapeutic substances in Hill. Whether any of those substances, if they were included, would even be absorbed, is not known from anything in Hill or the Examiner's Answer.

Second, the experimental results from the studies reported on pages 25-31 show that a greater than 30% increase in the medicament delivery rate is not always going to occur simply from adding sodium bicarbonate to the product. The sweetener material used to make the coating, as well as the amount of sodium bicarbonate, have an effect on caffeine delivery rates. Thus there is nothing in Hill or the Examiner's Answer that would suggest that any of the therapeutic substances in Hill would be absorbed 30% faster if sodium bicarbonate were used that if it were not. Thus the limitation of claim 37 is not inherent in Hill.

B. Claims 28, 29, 35, 36 and 38 are patentable over Hill in view of U.S. Patent No. 5,487,902 (Anderson) and WO 98/23165 (Gudas).

1. Claims 28 and 35

The Examiner's Answer makes a serious misstatement about the teachings of the prior art. Perhaps this misstatement is actually believed by the Examiner, giving rise to the making of the obviousness rejection of claims 28, 29, 35, 36 and 38 in the first place. On page 4 of the Answer, the Examiner states, "Anderson et al suggests that caffeine and benzocaine may be used alternatively as medicament active agents in chewing gum." Later on the same page the Answer states. "Anderson et al suggest the use of caffeine as an alternative to benzocaine." There is no suggestion in Anderson

that caffeine can be used as an alternative to benzocaine. Anderson discloses a type of solubilizer that could be included in a chewing gum composition to accelerate the release of active agents from the chewing gum. In column 8, lines 46-62, Anderson states that the invention has proved advantageous for controlled, accelerated release of active agents selected from various groups, and gives examples of the active agents in those groups. Benzocaine is listed as one example. "Coffeine" (believed to be a misspelling of "caffeine") is listed as another example. However, other medicaments are also listed. All of these active agents are used for different purposes in the chewing gum. There is no suggestion in this paragraph that any of these active agents may be substituted for one another, let alone that caffeine can be used as an alternative to benzocaine. Thus, the only thing that Anderson teaches that caffeine and benzocaine have in common is that they were both given an advantageous, controlled release from chewing gum when the solubilizer of Anderson was added to the gum composition.

This teaching does not provide a suggestion to modify the teachings of Hill to use caffeine in the Hill oral hygiene product. Hill discloses an emulsion coating on chewing gum to inhibit plaque adhesion to teeth. The therapeutic materials in Hill are all directed to the oral hygiene aspect of Hill. The whole idea of the invention of Hill is that one can make an emulsion coating on chewing gum to provide a disruption to the plaque growth in the oral cavity. Caffeine has nothing to do with oral hygiene. There would be no suggestion from Anderson to use caffeine in an oral hygiene product. There is no motivation from Anderson to use caffeine instead of benzocaine in the emulsion coating of Hill.

The Answer argues that Anderson suggests the use of caffeine and benzocaine in the "same environment, viz. chewing gum", and thus it becomes obvious to substitute caffeine for benzocaine in the chewing gum of Hill. This "same environment" argument completely fails to take into account why benzocaine is used in Hill, and even why benzocaine, caffeine, or one of many other medicaments are used in Anderson. The fact that one reference teaches that a medicament can be used in chewing gum does not provide motivation to use the same medicament in all other chewing gum compositions. An obviousness rejection must be based on a motivation to combine the teachings of the references. There is nothing in Anderson that would suggest using

caffeine in the Hill product, and there is nothing in Hill, which teaches an oral hygiene product, that would suggest that caffeine be added to the gum, or used in place of benzocaine, which does have an oral hygiene benefit. The Answer makes it even clearer that the Section 103 rejection is improper and must be reversed.

The Answer is silent as to the evidence of unexpected results shown in the test results on pages 25-31 of the specification. There is no question that the specification provides evidence of the unexpected results of the claimed composition. There is no suggestion in Hill of any reason to even consider bucal absorption. The therapeutic materials optionally suggested in Hill are all of the type that have an oral hygiene impact in the area of application. They are not active agents that are designed to be absorbed in the blood steam and travel to a distant point to have a therapeutic effect. Thus there is nothing in Hill that even hints at bucal absorption, let alone suggests that if sodium bicarbonate is added to a chewing gum product that has xylitol and/or sorbitol in a coating on the product, a medicament also found in the coating would be absorbed more quickly than if the sodium bicarbonate were not present. This unexpected result overcomes any *prima facia* case of obviousness that may be made it, either from the picking and choosing from the various optional ingredients in Hill by itself, or from any hindsight combination of Hill and Anderson.

2. Claims 29, 36 and 38

The Answer does not refute the point made in the Brief, that there is nothing in Gudas, or the other cited references for that matter, that would suggest using an encapsulated caffeine material in the product of Hill. As noted above, Hill is an oral hygiene product. There is no reason from Gudas that a person would be motivated to substitute encapsulated caffeine for benzocaine in Hill.

C. CONCLUSION

The Examiner's Answer does not refute that Appellants have made a novel and nonobvious contribution to the art of accelerating the absorption of medicaments through the oral mucosa. Rather, the Answer further demonstrates that the Section 102 rejection is inappropriate, based on picking and choosing different parts of the Hill reference, and that the obviousness rejection is likewise based solely on hindsight reconstruction of the invention. The Final Rejection should therefore be reversed.

Respectfully submitted,

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Dated: August 29, 2005
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